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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,456	11/02/2001	Timothy R. Owens	5618P2971	5019

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EXAMINER

ROY, BAISAKHI

ART UNIT PAPER NUMBER

3737

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/008,456

Applicant(s)

OWENS ET AL.

Examiner

Baisakhi Roy

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 12/27/05 have been fully considered but they are not persuasive. Applicant's attention is redirected to Gillies et al. teaching the adjustment of the visibility of the medical device based on the requirements (col. 23 lines 37-45), to either increase or suppress noise associated with the device. With respect to the storage of the target markers, applicant claims that the information of the markers is not stored prior to the insertion of the medical device into the anatomy and it is not clear as to the reasoning behind the storage of information on the markers when the device has not even been inserted into the anatomy. Also, in the applicant's arguments, in page 13, it appears that there should be storage of information of the target markers since it is stated in line 2 that nowhere in the Gillies reference is it taught, disclosed, or suggested that prior to insertion of the device, information of the markers is stored, whereas the claim states that prior to insertion of device, there should not be storage of information on the target markers.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention. With respect to the storage of the target markers, applicant claims that the information of the markers is not stored prior to the insertion of the medical device into the anatomy and it is not clear as to the reasoning behind the storage of information on the markers when the device has not even been inserted into the anatomy.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to the storage of the target markers, applicant claims that the information of the markers is not stored prior to the insertion of the medical device into the anatomy and it is not clear as to the reasoning behind the storage of information on the markers when the device has not even been inserted into the anatomy.

***Claim Rejections - 35 USC § 102***

1. Claims 1, 4-10, 13-24, 27-35, 38-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Gillies et al. (6272370).

Regarding claims 1, 4, 7-9, 13, 16, 19-22, 23, 27, 33, 34, 38, and 44, Gillies et al. teach an apparatus and method of inserting a medical device such as a catheter with a plurality of target markers into an anatomy, scanning a MRI image of the anatomy with said MRI processor having the ability to detect low-level signals, processing the scanned image, determining a location and orientation of the medical device in relation

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to the anatomy, and displaying a precise image of the device within the anatomy where the device is not depicted as noise for MRI systems (col. 6 lines 27-49, col. 8 lines 16-31, col. 11 lines 5-13, col. 14 lines 41-60, col. 27 lines 7-40).

Regarding claims 10, 24, 32, 35 and 43, Gillies et al. teach said method and apparatus pre-scanning the medical device before inserting in an anatomy, storing and transmitting a plurality of image data to the processor, and withdrawing the device from the anatomy at an adjusted pace (col. 11 lines 5-18, col. 12 lines 37-55, col. 28 lines 55-67).

Regarding claims 5, 6, 14, 15, 28, 29, 39, and 40, Gillies et al. teach said medical device to be expandable and composed of polymer material (col. 25 lines 15-25, col. 28 lines 52-55).

Regarding claims 17, 18, 30, 31, 41, and 42, Gillies et al. teach superimposing an image of the medical device over the anatomy by replacing a plurality of pixels of an anatomy with a plurality of pixels of the medical device (col. 11 lines 5-13 lines 31-64).

Regarding claims 45-49, Gillies et al. teach a MRI system comprising a scanner, a processor, a control unit, and a display with the ability to detect low-level signals from a medical device with a plurality of target markers which is inserted into an anatomy, where the device is not depicted as noise for MRI systems, and the location and orientation of said device is determined prior to insertion into an anatomy (col. 6 lines 27-49, col. 8 lines 16-31, col. 11 lines 5-13, col. 14 lines 41-60, col. 27 lines 7-40).

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2, 3, 11, 12, 25, 26, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gillies et al. in view of Young et al.

Regarding claims 2, 11, 25, and 36, Gillies et al. teach the use of a plurality of target markers as set forth above, but do not explicitly teach said markers to be one of ferromagnetic and paramagnetic material. In the same field of endeavor, Young et al. teach said medical device to be composed of paramagnetic material (col. 6 lines 34-65, col. 12 lines 37-67, col. 13 lines 1-20). It would have therefore been obvious to one of ordinary skill in the art to use the marker material composition teaching by Gillies et al. to modify the teaching by Young et al. for the purpose of using a paramagnetic material to generate images with enhanced visibility of the medical device.

Regarding claims 3, 12, 26, and 37, Gillies et al. do not explicitly teach the magnetic field strength of the MRI system. It is well known in the art that diagnostic MRI system employ magnets with operating field strengths in the range of 0.02 T to 1.5 T. In the same field of endeavor, Young et al. teach the use of a MRI system operating at 1.5 Tesla (col. 14 lines 10-15). It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Young et al. to modify the teaching by Gillies et al. for the purpose of applying an appropriate magnetic field strength.

***Conclusion***

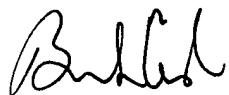
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BR

BR

  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
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